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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,068	10/23/2003	Graham Sommer	STFUP145/S03-109	2220
58766	7590	09/08/2008		
Beyer Law Group LLP P.O. BOX 1687 Cupertino, CA 95015-1687			EXAMINER LAMPRECHT, JOEL	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 09/08/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/693,068	Applicant(s) SOMMER, GRAHAM	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/8/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claims 10-14 objected to because of the following informalities: Regarding claim 10, the claim fails to positively set forth a step of providing a radiographic contrast agent to the blood. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims fail to provide a sufficient tie to another statutory class, such as an apparatus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gronberg et al (US 4,573,181). Gronberg et al discloses a method for measuring renal function as a component of x-ray fluorescence and CT analysis (Col 1 Line 63-Col 2 Line 20) through analysis of the change in concentration of contrast agent through the kidney and

associated vasculature (Col 1 Line 63-Col 2 Line 60). Iodine-based contrast agents are utilized and renal function is comparatively measured (Claim 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gronberg et al (US 4,573,181) in view of Unger (5,846,517). Gronberg et al discloses a method for measuring renal function as a component of x-ray fluorescence and CT analysis (Col 1 Line 63-Col 2 Line 20) through analysis of the change in concentration of contrast agent through the kidney and associated vasculature (Col 1 Line 63-Col 2 Line 60). Iodine-based contrast agents are utilized and renal function is comparatively measured (Claim 1). Gronberg et al do not disclose the specific use of iohexol, iothalamate, gadolinium-DTPA, nor do they describe a measurement of *renal extraction fraction* based on CT number of corresponding images which are acquired. Attention is directed to the secondary reference by Unger which discloses in detail renal function methods involving Gd-DTPA and discloses the knowledge of iodine preparations for CT specific image analysis (The remainder of the chemical composition is disclosed in their discussion on tagging molecules and volatile components) (Col 2 Line 35-Col 3 Line 5) and they make reference to US 5,205,290 for a description of analysis of CT number as

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relates to analysis of any CT image (specifically those with contrast agents).

Additionally Unger discloses a method of blood-based analysis of contrast agent concentration through comparative analysis of blood before, during and after administration of a contrast agent (Col 12 Line 60-Col 13 Line 53, Col 50 Line 65- Col 51 Line 25, Col 51 Line 58-64, Col 56 Line 35-Col 58 Line 20 for quantitative analysis).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the analysis techniques and further contrast agents disclosed by Unger with the methods described by Gronberg et al for the purpose of providing a CT analysis of a variation in renal function and further diagnosis of renal diseases or variations.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6,071,494 to Unger discloses further renal analysis techniques, 6,226,352 discloses further radiographic imaging techniques including those with contrast agents, 6,506,364 B1 to Simon et al discloses further radio-iodinated compounds and specific methods for making those compounds to assess renal function, 6,733,744 B1 to Achilefu et al discloses further methods for making Indole compounds for the purpose of providing functional diagnosis of physiological function in the kidney, and 6,852,842 to Brechibel et al discloses a method for MRI imaging of kidneys using a function of arterial blood analysis near the kidney and the difference between the extracted contrast and kidney volume. 6,122,540 to Katzberg et al discloses a method of providing renal extraction function using MRI and MR contrast.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JML